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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT PAPER NUMBER

1636

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16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/826,909

Applicant(s)

MOECKEL ET AL.

Examiner

Konstantina Katcheves

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-- The MAILING DATE of this c mmunication appears n the cover sheet with the c rrespondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to Paper No. 15, filed 13 February 2003. Claims 1-18 are pending in the present application. Claims 17 and 18 are withdrawn from consideration. Accordingly, claims 1-16 are pending in the present application.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-16 and the gene *dapA* in Paper No. 15 is acknowledged. The traversal is on the grounds: (1) that the examiner has not provided sufficient reasons to support the restriction between Groups I and II, (2) that a search of all claims would not be a serious search burden and (3) that there is no patentable distinction between the genes recited in claims 13, 14 and 15.

As stated in the prior Office Action but repeated and clarified herein for Applicant's benefit, The method of Group I comprises steps which are not required for or present in the method of Group II such as: (1) the preparation of L-amino acids in Group I; (2) the screening of RNA, cDNA or DNA using arrays, microarrays or DNA chips. Thus, the operation, function and effects of these different methods are different and distinct from each other. Moreover, the end results of each of these methods differ. The DNA, vector and host cell of Group I are not used in the methods of Groups II. The operation, function and effects of the DNA, vector and host cell of Group I (*i.e.* to make L-amino acids) are completely different and distinct from the operation, function and effects of the method of Group II which screen RNA, cDNA or DNA for polynucleotides or genes that encode for transcription regulators of *LysR2* using probes. Therefore, the inventions of these different, distinct groups are capable of supporting separate

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patents. Applicant's assertion that no serious search burden exists is untenable. Because these inventions are separate methods with separate method steps and outcomes as described above, a search for one group would not necessarily be adequate for the other group, thus, presenting a serious search burden to the examiner.

Regarding the election of dap1 as the gene for examination, the election of dapA is not an election of species requiring the expansions of the search to other species. Rather the genes of claims 13, 14 and 15 are subject to a restriction requirement because they are patentably distinct. Applicant asserts that the office has not provided reasons why these genes are patentably distinct and thus subject to a restriction requirement. These genes differ functionally, biologically and structurally from each other such that restriction is proper. For instance, dapA codes for dihydrodipicolinate synthase, eno codes for enolase, zwf codes for the zwf gene product and lysE codes for lysine export. This list shows that each of these genes encodes for enzymes or gene products with different and unrelated structures and functions such that restriction between the genes of the claim is proper.

The requirement is still deemed proper and is therefore made FINAL. Accordingly, claims 1-16 insofar as they read on dapA are currently under examination.

Claim Objections

Claims 13, 14 and 15 are objected to because they recite non-elected subject matter. Appropriate correction is required.

Claim 16 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must be stated in the alternative. See MPEP § 608.01(n).

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The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Claims 6, 13, 14 and 15 recite a non-conventional numbering scheme. Each claim should be numbered consecutively with an integer. If applicant chooses to outline elements in the claim in a step-wise manner, this should be done using a conventional outline format such as that found in claims 1 or 4 in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: “*specification* shall contain a written description of the invention. . .[emphasis added].” The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that “as of

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the filing date sought, [the inventor] was in possession of the invention.” See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in “possession” of the invention claimed by describing the invention with all of its claimed limitations “by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The present claims are drawn to: (1) polynucleotides having 70% identity to the polynucleotide of SEQ ID NO:1; (2) polynucleotides having 70% identity to the amino acid sequence encoded by SEQ ID NO:1; (3) polynucleotides complementary to those having 70% identity to the amino acid sequence or nucleic acid sequence of SEQ ID NO:1; (4) oligonucleotides of at least 15 nucleic acids in length from any of the above sequences. The claims also recite vectors and bacteria wherein the LysR2 gene is attenuated, yet activity remains. These sequences possess the activity of the transcription regulator LysR2.

These claims read on a broad genus of polynucleotides. However, neither the claims nor the specification as filed indicate what distinguishing attributes the members of the claimed genus of polynucleotides share. The specification and claims do not place any limit on the number of substitutions, deletions, insertions and/or additions that may be made to the claimed polynucleotides. It is only required that the nucleotide sequence maintain a some identity to SEQ ID NO:1. Moreover, the structural characteristics of the broad genus of polynucleotides embraced by LysR2 have not sufficiently been defined, and a single example of SEQ ID NO:1 fails to correct this deficiency. Thus, the scope of the claims includes numerous structural variants. The specification teaches and the claims recite that the sequences possess the activity

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of the transcription regulator, LysR2. However, no structural features are taught for these sequences wherein the activity of LysR2 would be maintained.

There are no common structural attributes shared among the members of the claimed genus of polypeptides that would allow one of skill in the art to clearly distinguish the members of this genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is required. The specification neither discloses any of these variant, modifications or fragments nor does it provide any teachings as to how the structures of these sequences relate to their function. Thus, the specification does not describe the complete structure of a representative number of species. The specification also fails describe a representative number of species in terms of partial structure and relevant identifying characteristics. Absent teachings and guidance as to the structure-function relationship of these molecules, the specification does not describe the claimed recombinant DNA molecules in such full, clear, concise and exact terms so as to indicate that Applicant had possession of these molecules at the time of filing of the present application. Thus, the written description requirement has not been satisfied.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The present claims recite words such as “preferably,” “optionally” and “in particular.” The claims also recite words or letters in parenthesis such as in claim 11. This use of language and grammar does not make clear whether applicant wants to include the statement following these terms as limitations in the claims. These words are not definitive such that one of skill in the art would be apprised of the metes and bounds of the claim.

Claim 10 recites the language “partly eliminate.” Eliminate connotes an absolute condition. It is not clear how something can be partly eliminated if the word means that something is eradicated or completely removed.

The present claims such as claim 9 recite the words “additionally enhanced” or “enhanced.” It is not clear from the claims or specification what applicant intends this word to mean. Is enhance supposed to mean an increase in expression, an increase in activity or something else completely?

Claim 6 refers to figure 1. Generally, it is appropriate to refer to a figure in a claim only when there is no other adequate way of claiming the invention. According to MPEP 2173.05(s):

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table “is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant’s convenience.” *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993).

Thus, claim 6 requires correction.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
April 24, 2003


JAMES KETTER
PRIMARY EXAMINER